PATENT

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Monique X. Le

Applicant	:	Kevin Woehr	Confirmation No. 5105
Application No.	:	10/520,325	
Filed	:	September 12, 2005	
Title	:	CATHETER INSERTION DEVICE	
Grp./Div.	:	3767	
Examiner	:	Michael J. Anderson	
Docket No.	:	22145	

APPELLANT'S BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

43 Corporate Park, Suite 204
Irvine, CA 92606
July 2, 2008

Commissioner:

This is an appeal to the Board of Patent Appeals and Interferences from the Final Rejection, dated November 14, 2007, in which Claims 1-20 of the above-referenced application stand rejected. A Notice of Appeal was filed on April 14, 2008.

1. REAL PARTY IN INTEREST

B. Braun Melsungen, A.G.

2. RELATED APPEALS AND INTERFERENCES

There are no related Appeals and/or Interferences.

3. STATUS OF CLAIMS

Claims 1-20 are finally rejected and are on appeal. Claims 1 and 12-20 were previously presented.

4. STATUS OF AMENDMENTS

No amendments have been made since the Final Office Action of November 14, 2007. Claims 1 and 12-20 were previously presented.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Claims 1, 10, and 11 are independent claims.

Claim 1 is directed to a catheter insertion device comprising a catheter hub having an interior cavity for accommodating both a check valve and a needle guard and a needle hub having a needle projecting through the catheter hub, check valve, and needle guard in a ready to use position. The needle guard and check valve are configured such that the needle guard is displaceable away from the catheter hub when in a used position. FIGs. 1-4, reproduced below, for example, are representative of the claimed catheter insertion device. Paragraphs [0016] to [0025].

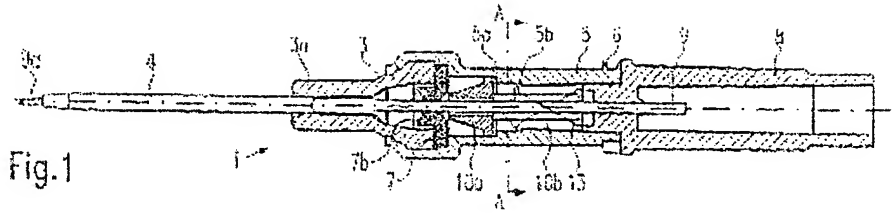


Fig.1

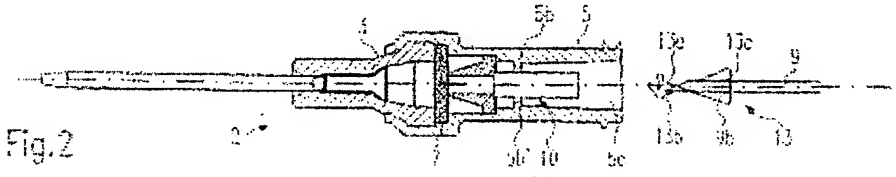


Fig.2

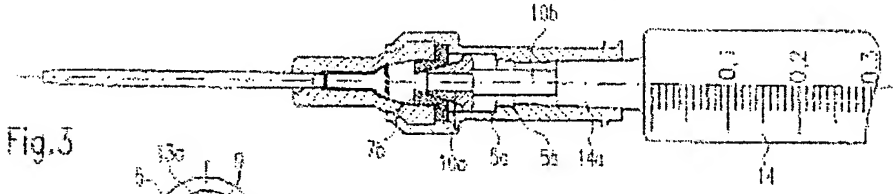


Fig.3

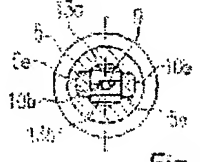


Fig. 4

Dependent claim 4, which depends from claim 1, is further directed to the catheter hub having a radial projection projecting radially to engage with the needle guard element in the ready position. This is shown in FIGs. 1 and 3, for example, as element 5b. Paragraph [0023].

Dependent claim 5, which depends from claim 1, is further directed to a valve actuating element, which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element. This is shown more clearly in FIGs. 1 and 4, for example, and paragraph [0017].

Dependent claim 6, which depends from claim 5, is further directed to the valve actuating element and specifies that it is formed as a hollow cylinder with a truncated cone-shaped distal end section. This is shown in FIGs. 1-3, for example, as element 10a. Paragraph [0021].

Independent claim 10 is directed to a catheter insertion device, similar to claim 1 but focuses on a different aspect of the assembly of FIGs. 1-4. In particular, claim 10 calls out a catheter hub having an interior cavity for accommodating both a check valve and a needle guard and a needle hub having a needle projecting through the catheter hub, check valve, and needle

guard in a ready to use position. The needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve. Paragraphs [0016] to [0025] and in particular FIG. 1, which shows two arms crossing the needle axis.

Dependent claim 15, which depends from claim 10, is further directed to an actuating element for opening the valve, the actuating element comprising two plunger sections comprising a space therebetween for accommodating the needle guard. This is shown in FIGs. 1, for example, and 4 and in paragraph [0017].

Independent claim 11 is directed to a catheter insertion device, similar to claim 1 but focuses on a different aspect of the assembly of FIGs. 1-4. In particular, claim 10 calls out a catheter hub having an interior cavity for accommodating both a check valve and a needle guard and a needle hub having a needle projecting through the catheter hub, check valve, and needle guard in a ready to use position. The needle guard is configured to contact an engaging section of the needle and the needle guard is located between the valve and the needle hub. Paragraphs [0016] to [0025] and in particular paragraph [0018].

Dependent claim 17, which depends from claim 11, is further directed the needle guard wherein at least one arm comprising an apex abutting a shoulder located on the interior surface of the catheter hub. This is shown in FIG. 1, for example, and paragraphs [0023] and [0025].

Dependent claim 19, which depends from claim 11, is further directed to an actuating element for opening the valve, the actuating element comprising two plunger sections comprising a space therebetween for accommodating the needle guard. This is shown more clearly in FIGs. 1 and 4, for example, and paragraph [0017].

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether the Examiner erred in rejecting claims 1-20 under 35 USC §103(a) as being unpatentable for obviousness by Woehr et al. (USP 6,117,108) or Woehr et al. (USP 6,287,278) in view of Rogers et al. (USP 5,405,323).

7. ARGUMENT

Woehr in view of Rogers Does Not Render Claims 1-20 Obvious

Claims 1-20 are rejected under §103(a) as being unpatentable over Woehr et al. ('108 patent) in view of Rogers ('323 patent), (Page 2 of Final Action). However, on Page 4 of the Final Action, the Examiner refers to the '278 Woehr reference and then in the immediate next paragraph and subsequent paragraphs, jumps to the '108 Woehr reference. Finally, on page 6 of the Final Action, the Examiner relies on both the '108 Woehr reference and the '278 Woehr reference in combination with the '323 Rogers reference to reject claims 12-20.

As the '278 Woehr reference is a CIP of the '108 Woehr reference and both patents are relied on for the same proposition, the discussion below for the '108 Woehr reference in combination with the '323 Roger reference will apply equally as if the combination was for the '278 Woehr reference and the '323 Roger reference.

Obviousness under 35 USC §103(a) is established as follows:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

In 2007, the KSR Supreme Court reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Furthermore, according to MPEP §2141, "Office personnel . . .[to perform the] critical role of factfinder when resolving the *Graham* inquiries. . . Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness."

Under 35 U.S.C. 132, a well articulated and reasoned Office Action is required so that an applicant may be properly notified of the reasons for the rejection of the claim so that he or she can then decide how best to proceed. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should

be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. The "mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness." *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976). MPEP §2141(III).

Once Office personnel have established the *Graham* factual findings and conclude that the claimed invention would have been obvious, the burden then shifts to the applicant to (A) show that the Office erred in these findings or (B) provide other evidence to show that the claimed subject matter would have been nonobvious. Examples of rebuttal evidence include (MPEP §2141(V)):

(A) one of ordinary skill in the art could not have combined the claimed elements by known methods (e.g., due to technological difficulties);

(B) the elements in combination do not merely perform the function that each element performs separately; or

(C) the results of the claimed combination were unexpected.

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). MPEP §2143.02.

The '108 Woehr Reference

The '108 reference is directed to a spring clip safety IV catheter. According to the Abstract section of the '108 patent:

> A safety IV catheter includes a unitary, resilient needle guard received in a catheter hub. The needle guard includes a proximal arm or wall that includes an opening through which a needle passes for axial movement. When the needle is retracted from the catheter it releases the force that had previously prevented movement of the needle guard within the catheter hub. This in turn causes the needle guard to snap into a position in which it is clamped onto the needle shaft and in which its distal wall blocks access to the needle tip. In this condition, the spring needle guard and needle can be removed from the catheter hub. A slot or bulge may be formed in the needle shaft that engages with the needle guard after the protected needle and needle guard are removed from the catheter hub, thereby to prevent removal of the protected needle from the needle guard. (Abstract)

FIG. 10A, reproduced below, is representative of the catheter assembly disclosed by the '108 patent while FIG. 10B is representative of the same assembly following an injection, or used position.

Fig. 10A

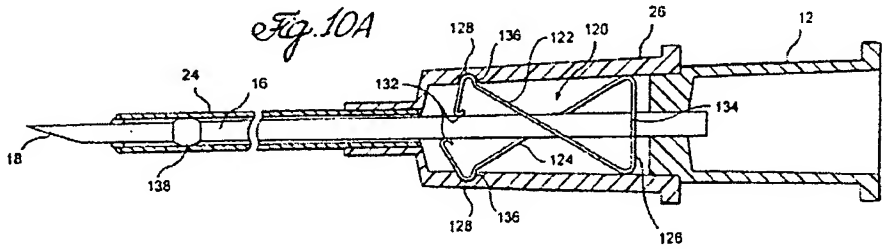


Fig. 10B

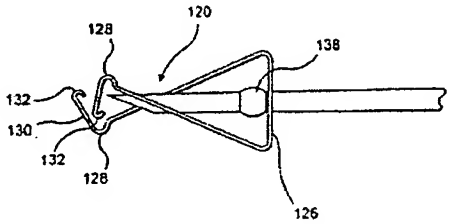


FIG. 10A shows a needle hub 12 having a needle 18 projected through a needle guard 120, catheter hub 26, and catheter tube 24. The needle guard 120 has two arms 122, 124 and corresponding curved protrusions 128 for engaging with corresponding annular grooves 136.

(Col. 8, lines 43-52). This allows the guard to be retained within the cavity of the catheter hub 26 when the needle is retracted during use. (Col. 8, lines 4-50).

As clearly shown in FIG. 10A and discussed in the specification (Col. 8, lines 43-52), "the needle shaft passes through the needle guard and applies an outward radial force on resilient arms 122, 124 by means of its engagement with lips 132, so as to urge the curved protrusions 128 of each of the arms into the annular groove 136, so as to retain needle guard 120 in a fixed position within the inner wall of catheter hub 26. The shaft of needle 16 that passes through the needle guard 120 frictionally engages the inner edges of the narrow portions 142 of arms 122, 124 so as to further retain the needle in its ready position."

However, the needle shaft and the guard must be configured such that when the needle is withdrawn from the catheter hub, the two arms of the needle guard closes over the needle tip to shield the needle tip, as shown in FIG. 10B. This arrangement was disclosed in the '108 Woehr patent as follows:

> When the needle is retracted axially within the catheter hub, and moves past the end lips 132 of the needle guard, the radial force previously exerted on arms 122, 124 of needle guard 120 is suddenly released. This causes the distal end walls 130 of the needle guard to be released from their seat in the annular groove 136 and to pivot inwards into the catheter hub until, as seen in FIG. 10B, the end walls 130 overlap one another at a location distally in front of the needle tip, thereby to form a barrier that prevents inadvertent contact with the needle tip. At the same time, the clamping edges 146 of the needle guard (FIG. 11B) are urged against the needle tip to restrict further axial movement of the needle. (Col. 8:53-65).

Thus, the interplay between the needle shaft, the needle guard, and the interior cavity of the catheter hub is important in both positioning the guard in a ready to use position and allowing the guard to dislodge from the catheter hub and shield the needle in the used position. As further discussed below, this interplay is no longer available when the needle guard is mounted over the valve disclosed by the '323 Rogers patent.

The '323 Rogers reference

The '323 Rogers patent is relied on to disclose a check valve assembly. FIGs. 1, 3, and 4 reproduced below are representative of the '323 patent.

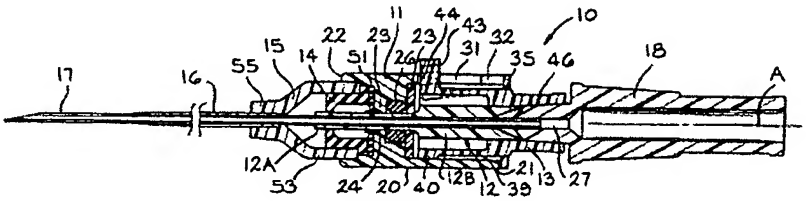


FIG. 1

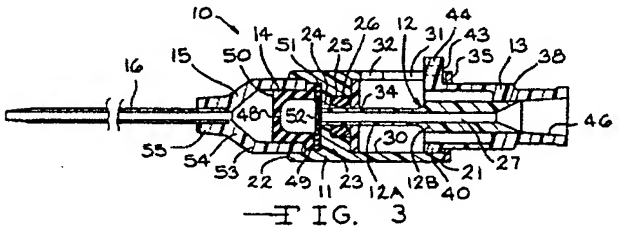


FIG. 3

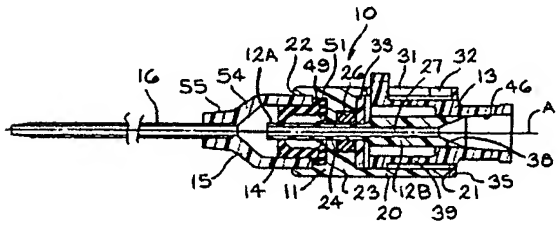


FIG. 4

According to the Abstract of the '323 patent:

A catheter check valve assembly has a body member with a wall defining a generally cylindrical chamber and a transverse wall having an aperture lying on the axis of such chamber. A duckbill valve and an end cap supporting a catheter are positioned on one side of the transverse wall. A separator has a major portion positioned in said cylindrical chamber and an elongated cylindrical probe extending from said major portion. The separator is axially moveable from a retracted position where the probe is out of contact with the duckbill valve to a forward position extending through and opening the duckbill valve. A trocar may be extended through the catheter check valve assembly when the separator is in the forward position. (Abstract, emphasis added).

Thus, according to the Abstract, a major portion of "a separator" is positioned within the catheter hub to interact with the duckbill valve.

With reference to FIGs. 1, 3 and 4 produced above, Rogers describes a catheter check valve assembly 10 as including a body member 11, a separator 12, a separator body 13, a duckbill valve 14, and an end cap 15, which has a catheter tube 16 secured thereto. The separator body 13 incorporates a finger tab 44, called a "head", for moving the separator 13 from between an IV infusion position, FIG. 3 (See also Col. 4:40-49), and a blood sampling position, FIG. 4 (See also Col. 4:56-62). As described in the '323 patent specification, when the assembly 10 is in the blood sampling mode, FIG. 4, a user "move[s] the separator 12 and separator body 13 to the forward position shown in FIG. 4, thus opening duckbill valve 14 and permitting blood sample to be removed through the passageway 27."

The '323 patent further describes movement of the separator body 13 and the post 43 within a longitudinal slot 31 as follows:

> The post 43, upon assembly of the separator body 13 to the body member 11, extends through the longitudinal slot 31 and is moveable therein as the separator body 13 carrying the separator 12 is moved from a retracted position shown in FIGS. 2, 3 and 5, to a forward position shown in FIGS. 1 and 4. Those portions of the post 43 above and below the central area 45 (as viewed in FIGS. 7 and 8) have a breadth greater than the width of the central portion of the longitudinal slot 31 but smaller than the width of the enlarged areas 32 at each end of the slot. When the separator body 13 is in the forward or retracted position, the post 43 is retained in one of the enlarged areas 32 so that the separator body 13 and the separator 12 carried thereby are retained in such forward or retracted position. When it is desired to move the separator body 13 from the retracted position to the forward position or from the forward position to the retracted position, the post 43 is depressed by pushing downwardly on the head 44 to move the tab 42 and the post 43 to a position at which the central area 45 of reduced breadth becomes aligned with the narrow central portion of slot 31 as shown in FIG. 8. Such alignment permits the separator body 13 and the separator 12 to be moved axially between a retracted and a forward position with the central area 45

moving through the slot 31 from one enlarged area 32 to the other. (Col. 3, lines 30-55).

Based on the foregoing, it is clear that the Rogers device requires clearance within the interior cavity of the body member 11 so that the separator 12 can traverse forward and rearward between an IV infusion position and a blood sampling position to penetrate through the valve.

The Final Office Action

In rejecting claims 1, 4, 7, and 9, the Examiner contends that Woehr ('108) discloses a catheter insertion device (10) comprising a hollow-cylindrical catheter hub (26), catheter tube (24), needle hub (12), a hollow needle (16), a needle guard element (40) on the needle within the catheter hub (36) and an engaging section, which is configured to engage with the needle guard element in the ready position. (Page 3 Final Action). The Examiner then made the following assumption:

> "However, Woehr lacks a check valve disposed between the catheter tube (16) and the needle guard element (26 and 33) in the catheter hub (13) through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle (figures 1 and 2 and Col. 3, lines 30-55 and Col. 4, lines 23-62). Since the function of catheters is to allow controlled delivery of medicaments or removal of blood from a patient's vessel, it would have been obvious to one of ordinary skill in the art to modify Woehr's catheter insertion device with a check valve to control intravenous fluid transmission and fluid sampling by closing the fluid pathway after removing the needle." (Page 3-4, Final Action).

The Claimed Invention

Claim 1

Woehr in view of Rogers does not render claim 1 obvious. To show that the device taught by Woehr and by Rogers are not compatible, will not work as a combination, and teach away from one another, FIG. 1 of Rogers and FIG. 10A of Woehr are reproduced below. Additionally, the needle guard taught by Woehr is transposed over the hub section 11 and the

duckbill valve 14 taught by Rogers to highlight a nonsensical result produced by the suggested combination.

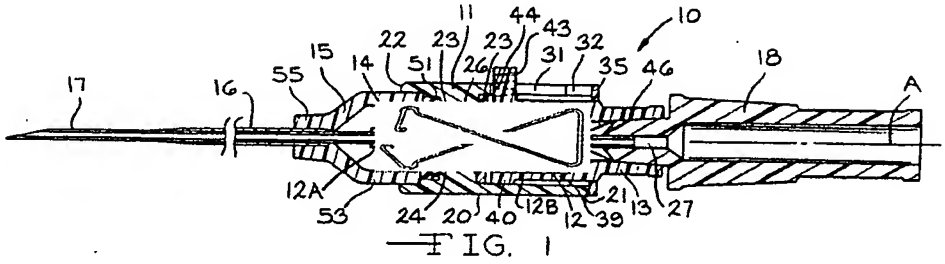


FIG. 1

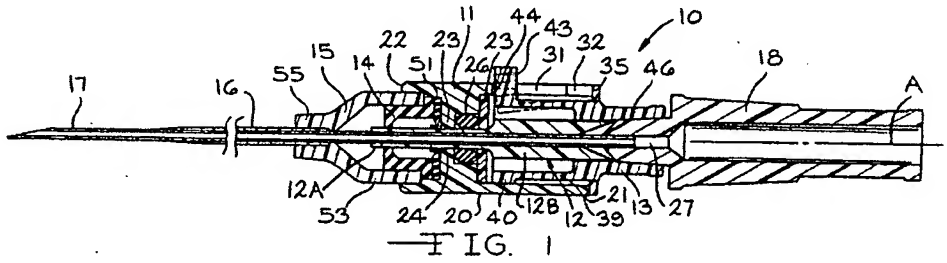
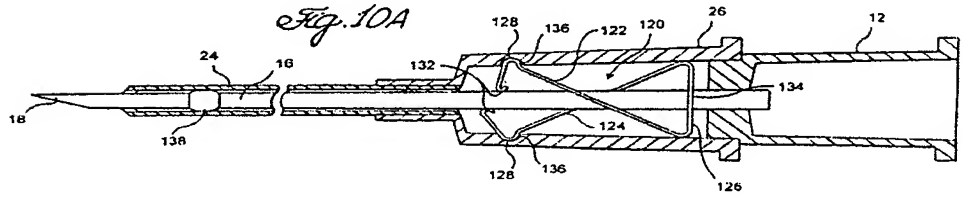


FIG. 1

Fig. 10A



In short, for the valve assembly 14 of the '323 Rogers patent to operate, the tubular portion 12A of the separator must project through both the annular seal 26 and the slit 48 (FIGs. 4 and 9) to provide a fluid pathway between the catheter tube 16 and the cavity at the luer lock fitting 46 (FIG. 3) of the body member 11. However, these components are present, then the needle guard could not be mounted, as shown in the combined figure.

Therefore, to use the check valve assembly disclosed by the '323 Rogers patent with the catheter device disclosed by the '108 Woehr patent would require significant changes in the arrangement of various elements and would impact the functionality of the needle guard element if the changes proposed by the Examiner were made. For example, the hub of the Woehr catheter device would need to be modified to accept the valve assembly taught by Rogers while at the same time accommodate the needle guard at a proximal position thereof. Furthermore, a

separator 12 and separator body 13 would project over the needle and the needle guard disclosed by the Woehr reference would be positioned over the forward tubular portion 12A, the rearward tubular portion 12B, or both portions of the separator in the Examiner's proposed modification but not where it needs to be, directly over the needle shaft and the two distal arm sections in contact with and biased by the needle shaft. Also, combining the two would require widening or expanding the diameter of the opening of the proximal wall of the Woehr needle guard, which would make the opening larger than the crimp 138 on the needle and therefore will not allow the guard to engage the needle in the protective position.

In the Examiner suggested combination, the clip disclosed by Woehr will be positioned over the tubular portion 12A disclosed by Rogers. The clip will never engage the needle as proposed by the Examiner. In other words, the tubular portion 12A disclosed by Rogers would act as a divider or wall and never allow the crimp on the needle to engage the guard to then separate the guard form the catheter hub in a used position to cover the needle tip. Accordingly, the proposed modification is defective and will not operate. As such, the two references cannot be combined to reject the claimed device without undue modification.

Also, as the separator body 12 in the Rogers reference incorporates a finger tab 44, called a "head", for moving the separator 13 from between an IV infusion position FIG. 3 (See also Col. 4:40-49) and a blood sampling position FIG. 4 (See also Col. 4:56-62), the Woehr clip cannot be mounted inside the interior cavity of the catheter hub or the two would interfere with one another.

Also, neither Woehr nor Rogers shows how these changes can be accomplished, which are not minor changes. Still furthermore, there is no indication whether even if the changes were made the combination would function or operate.

As set forth above, the key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. Appellant submits that one of ordinary skill in the art would not be motivated to modify the

Woehr '108 reference as suggested for the simple reason that the combination does not work and will destroy both the principle operation of the Woehr device and the Rogers device. Said differently, there is no motivation to combine the two references because the expected result is that they do not work in combination as suggested.

The elements in combination do not merely perform the function that each element performs separately. In the '108 Woehr reference, the clip engages the catheter hub in a ready to use position but disengages when the engagement section of the needle interacts with the proximal wall of the clip and the needle tip moves proximally of the two arms, which allows the two arms to snap over the distal tip of the needle. However, this requires physical interact between the clip and the catheter hub and the needle and the clip, which would be eliminated when mounted over the tubular portion 12A/12B of the separator 12.

Rogers discloses a device in which the separator 12 moves forward and rearward to open and close the valve and is co-axially mounted over the needle. Combining the clip disclosed by Woehr with Rogers will require mounting the clip over the rearward potion 12B or forward portion 12A or both of the separator 12 and therefore will never allow the needle guard to interact with the needle. This removes an operational feature of the Woehr device, the interaction between the clip and the needle to separate the clip from the catheter hub.

Appellant has raised similar arguments in a Request for Reconsideration filed February 6, 2008. However, in an Advisory Action dated March 4, 2008, the Examiner summarily concludes that "*the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.*" This statement fails to provide any articulated reasoning with a rational underpinning to support the legal conclusion of obviousness required by the KSR Court. It is not sufficient to merely point to a catheter device having a clip and a catheter device having a valve in the prior art. If so and unless an invention is directed to a new periodic table element, any combination would be deemed obvious by the Examiner's rationale. Appellant submits that the obviousness analysis is not complete until an explanation is provided as to why one having ordinary skill in the art would have been led to apply this teaching of a protective clip to a catheter check valve assembly in light of the physical difficulties and incompatibilities pointed out by Appellant. No such explanation was ever provided. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). MPEP §2143.02.

Still furthermore, independent claim 1 recites a catheter assembly wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub. In the overlay picture produced above, the guard disclosed by the '108 Woehr prior art reference would not be disposed between the catheter tube and the needle guard element in the catheter hub but instead positioned directly on top of the duck bill valve.

In view of the foregoing remarks, Appellant submits that the combination of Woehr in view of Rogers is defective as there is no reasonable expectation of success. Furthermore, even if combinable, a position which Appellant opposes, the combination does not show "wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle."

Reconsideration and rescission of the rejection are respectfully requested.

Dependent Claims 2-9

Because claims 2-9 depend, either directly or indirectly, from claim 1, they too are allowable for at least the same reasons.

Dependent Claim 4 – Separately Patentable

Dependent claim 4 recites "[t]he device according to claim 1, wherein the catheter hub comprises an inner circumference and a radial projection projecting radially from the inner circumference, which is configured to engage with the needle guard element in the ready position."

Although Page 3 of the Final Action shows that claim 4 is rejected by the '108 Woehr reference in view of the '323 Roger reference, the Examiner failed to set forth any reason whatsoever for the rejection.

Claim 4 makes clear the interaction between the needle guard and the catheter hub in the ready position. However, as Rogers uses a separator to move forward and backward, this separator will conflict when a needle guard is used with the valve disclosed by Rogers. The traversing separator will not allow for the combination to work.

As there is no reasonable expectation of success for the cited combination, claim 4 is separately patentable.

Dependent Claim 5 – Separately Patentable

Dependent claim 5 recites "The device according to claim 1, wherein the check valve comprises a valve disc, which has radial slits starting from a middle section of the valve disc, and a valve actuating element, which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element."

In rejecting claim 5, the Examiner contends that Woehr discloses essentially as shown except for a "valve actuating element . . . [having] a hollow space for receiving the needle guard element. . ." The Examiner then contends that Rogers discloses a "valve actuating element (12) displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element (34), and an actuating element formed as a hollow cylinder with a truncated cone-shaped distal end section Figure 2 and Col. 4, lines 23-62)."

Appellant submits that a review of FIG. 2 and Col. 4 lines 23-62 of the Rogers reference show NO such structures or features. Conversely, the Examiner's statements point out the precise engineering difficulties that would face a person of ordinary skill in the art in attempting such impossible feat. The valve actuating element, because it is displaceably guided in the catheter hub, would make adding a needle guard in the same catheter hub impossible, for the various reasons discussed above with reference the patentability of claim 1.

Furthermore, Appellant could not find "a valve actuating element, which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element" either in FIG. 2 or within the text of Col. 4, lines 23-62. The suggestion by the Examiner is difficult to imagine. Firstly, the '323 patent specification specifically states that the separator has a "tubular forward potion 12A. . . [and] a rearward portion 12B having a larger size, larger than the aperture 24 and, preferably, having a cylindrical exterior surface." (Col. 2, lines 50-54). This is clearly not a valve with a hollow space for receiving a needle guard. Second, if the separator 12 is provided with a "hollow space for receiving the needle guard", then the separator would not fit in the Luer lock fitting section 46 (FIG. 1 of Rogers) and would not penetrate through the traverse wall 23 of the annular seal 26. Thus, the ground for rejecting claim 5 is factually incorrect and non-operational if combined.

Independent Claim 10

Independent claim 10 recites, in part, a catheter insertion device comprising a catheter tube and a catheter hub comprising an interior cavity; a needle, said needle projecting, through the catheter tube; a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub; and a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve.

As set forth above for the allowance of claim 1, for the valve assembly 14 of the '323 Rogers patent to operate, the tubular portion 12A of the separator must project through both the annular seal 26 and the slit 48 (FIGs. 4 and 9) to provide a fluid pathway between the catheter tube 16 and the cavity at the luer lock fitting 46 (FIG. 3) of the body member 11.

Thus, to use the check valve assembly disclosed by the '323 Rogers patent with the catheter device disclosed by the '108 Woehr patent would require significant changes in the arrangement of various elements and would impact the functionality of the needle guard element if the changes proposed by the Examiner were made. For example, the hub of the Woehr catheter device would need to be modified to accept the valve assembly taught by Rogers while at the same time accommodates the guard at a proximal position thereof. Furthermore, a separator 12 and separator body would project over the needle and the needle guard disclosed by the Woehr reference would be positioned over the forward tubular portion 12A, the rearward tubular portion 12B, or both portions of the separator in the Examiner's proposed modification. However, doing so would first require widening or expanding the diameter of the opening of the proximal wall of the clip, which would make the opening larger than the crimp 138 on the needle and therefore will not engage the needle in the protective position. Also, neither Woehr nor Rogers show how these changes can be accomplished, which are not minor changes. Still furthermore, there is no indication whether even if the changes were made the combination would function or operate.

Claim 10 also makes clear that "needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve". If combined as suggested by the Examiner, this will necessary require the two arms to rest against the tubular portion 12B. However, in doing so, the arms would PERMANENTLY engage against the catheter hub since the tubular potion will never retract rearwardly to a point that it

allows the two arms to collapse to separate from the groove. Thus, the proposed solution is simply nonsensical.

Dependent Claims 12-15

Claims 12-15 depend, directly or indirectly, form claim 10. Accordingly, claims 12-15 are patentable over the combination of Woehr and Rogers for at least the same reasons as claim 10.

Dependent Claim 15 – Separately Patentable

Dependent claim 15, which depends from claim 10, further recites "The catheter insertion device of claim 10, further comprising an actuating element for opening the valve, the actuating element comprising two plunger sections comprising a space therebetween for accommodating the needle guard."

Claim 15 is similar to claim 5, with the exception of each claim's dependency. Thus, claim 15 is separately patentable over the combination of Woehr and Rogers as set forth above.

Independent claim 11

Independent claim 11 recites, in part, a catheter insertion device comprising a catheter tube attached to an end of a catheter hub, the catheter hub comprising an interior cavity; a needle, said needle projecting, through the lumen of the catheter tube and comprising an engaging section near a needle tip; a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub; and a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub.

Independent claim 11 recites features that are similar to independent claims 1 and 10, namely a device comprising a catheter hub, needle hub, a needle guard, and a valve. Appellant submits that the combination of Woehr in view of Rogers is defective and therefore not applicable to claim 11 for similar reasons as discussed above for claims 1 and 10.

Furthermore, even if the two references are combinable, the combination fails to disclose a device comprising "a needle guard element comprising an opening adapted to contact the

engaging section of the needle positioned between the valve and the needle hub". As discussed above, when combined, the needle guard disclosed by Woehr would necessary be mounted over the tubular portion of the separator. However, doing so would prevent the any possibility of the engaging section of the needle from engaging the opening on the needle guard. Accordingly, the combination fails to render claim 11 obvious as required under 35 USC §103(a).

Dependent claims 16-20

Claims 16-20 depend, directly or indirectly, form claim 11. Accordingly, claims 16-20 are patentable over the combination of Woehr and Rogers for at least the same reasons as claim 11.

Dependent Claim 19 – Separately Patentable

Dependent claim 19, which depends from claim 11, further recites "The catheter insertion device of claim 11, further comprising an actuating element for opening the valve, the actuating element comprising two plunger sections comprising a space therebetween for accommodating the needle guard."

Claim 19 is similar to claim 5, with the exception of each claim's dependency. Thus, claim 19 is separately patentable over the combination of Woehr and Rogers as set forth above.

8. CLAIM APPENDIX

1. A catheter insertion device comprising

a hollow-cylindrical catheter hub having a catheter tube attached at a distal end thereof, a needle hub having a hollow needle attached thereto and extending through the catheter hub and the catheter tube when in a ready position, a needle guard element arranged displaceably on the needle in the catheter hub and having an engaging section which engages with an engaging means formed near the needle tip when the hollow needle is removed from the catheter hub, wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle.

2. The device according to claim 1, wherein the catheter hub comprises a distal hub element and a proximal hub element, and the check valve is held between the distal hub element and the proximal hub element, which are joined to one another.

3. The device according to claim 1, wherein the check valve has a plurality of radially elastically expandable valve flaps configured to be moved into an open position by fluid pressure generated from a syringe.

4. The device according to claim 1, wherein the catheter hub comprises an inner circumference and a radial projection projecting radially from the inner circumference, which is configured to engage with the needle guard element in the ready position.

5. The device according to claim 1, wherein the check valve comprises a valve disc, which has radial slits starting from a middle section of the valve disc, and a valve actuating element, , which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element.

6. The device according to claim 5, wherein the valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section.

7. The device according to claim 6, wherein the hollow cylindrical valve actuating element comprises an inner circumference and a radial projection for positioning the needle guard element.

8. The device according to claim 5, wherein the valve actuating element has a truncated cone-shaped abutting section.

9. The device according to claim 1, wherein the needle guard element is formed as a spring clip which has diametrically opposite spring arms starting from a rear wall provided with a bore, wherein bent end sections of the spring arms overlap and block the needle tip when the engaging means of the needle comes to abut on the rear wall.

10. A catheter insertion device comprising:

a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity;

a needle defining a needle axis attached to an end of a needle hub, said needle projecting through the lumen of the catheter tube;

a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub; and

a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve.

11. A catheter insertion device comprising:

a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity;

a needle defining a needle axis attached to an end of a needle hub, said needle projecting, through the lumen of the catheter tube and comprising an engaging section near a needle tip;

a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub, said valve comprising an opening and the needle projecting through the opening; and

a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub.

12. The catheter insertion device of claim 10, wherein the two needle guard arms cross one another.

13. The catheter insertion device of claim 10, wherein the needle guard element comprises a proximal wall comprising an opening having the needle passing therethrough.

14. The catheter insertion device of claim 10, wherein the valve is a disc having at least one slit formed therein.

15. The catheter insertion device of claim 10, further comprising an actuating element for opening the valve, the actuating element comprising two plunger sections comprising a space therebetween for accommodating the needle guard.

16. The catheter insertion device of claim 11, wherein the engaging section is crimp.

17. The catheter insertion device of claim 11, wherein the needle guard further comprises at least one arm comprising an apex abutting a shoulder located on the interior surface of the catheter hub.

18. The catheter insertion device of claim 11, wherein the needle guard comprises two arms that intersect one another.

19. The catheter insertion device of claim 11, further comprising an actuating element for opening the valve, the actuating element comprising two plunger sections comprising a space therebetween for accommodating the needle guard.

20. The catheter insertion device of claim 11, wherein the needle guard is made from a metal material.

9. EVIDENCE APPENDIX

None.

10. RELATED PROCEEDING APPENDIX

None.

11. CONCLUSION

For the reasons stated above, Appellant submits that claims 1-20 are patentable over the Woehr reference in view of the Rogers reference. Reversal of the Examiner's decision is respectfully requested.

Respectfully submitted,

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